

REMARKS

Applicant acknowledges receipt of the Office Action (Paper 5) mailed May 6, 1997. Applicant thanks the Examiner for the careful attention accorded this application. Claims 15-22 are pending; Claims 18-19 have been withdrawn from consideration without prejudice or disclaimer of matter contained therein, and Claims 15-17, and 20-22 have been rejected. Reconsideration of the rejections and allowance of the Claims are respectfully requested in view of the foregoing amendments and the following remarks. Claims 16-17, and 22 have been amended. Claims 23-29 have been added.

Applicant confirms the election to prosecute Claims 15-17 and Claims 20-22 in response to the restriction requirement and reserves the right to prosecute the cancelled Claims by way of a divisional application pursuant to 35 U.S.C. § 121.

Support for new Claims 23-24, and 26-29 may be found *inter alia* in the Applicant's application, on page 4 line 27 through page 5 line 15 and the drawings Figs 1-2. Support for Claim 25 can be found *inter alia* in the Applicant's application, on page 5, line 34 through page 6, line 2; and page 6 lines 25-28. Applicant respectfully submits that no new matter has been added by way of the amendments.

OBJECTION TO DISCLOSURE

Applicant has amended the specification to reflect that application 08/346,066 is a division of application Serial No. 08/173,542, as requested by the Examiner.

Accordingly, applicant respectfully requests that the objection to the disclosure be withdrawn at this time.

REJECTIONS OF CLAIMS- 35 U.S.C. § 112 SECOND PARAGRAPH

Applicant respectfully disagrees with the rejections of Claim 16-17 under 35 U.S.C. § 112 second paragraph, however, Applicant submits that amendments to Claims 16-17 obviate the rejections.

Applicant respectfully submits that no new matter has been added by way of amendments to the Claims. Accordingly, Applicant respectfully requests that the rejection of Claims 16-17 under 35 U.S.C. § 112 second paragraph be withdrawn at this time.

REJECTIONS OF CLAIMS- 35 U.S.C. § 112 FIRST PARAGRAPH

Applicant respectfully disagrees with the rejections of Claim 15-17 and 20-22 under 35 U.S.C. § 112 first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention. More particularly, Applicant respectfully disagrees that "radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube" is not reasonably

conveyed by the original specification, is new matter, and that the original specification only supports allowing the stent to radially expand.

The term "allow" is defined *inter alia* in *Webster's Third New International Dictionary* (1993), for example, as "permit by way of concession"; "to permit by neglecting to constrain"; "to make a possibility"; and "provide opportunity or basis". Accordingly, Applicant respectfully submits that the positive recitation of radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube is reasonably conveyed by the original specification and one having ordinary skill in the art would have knowledge that a stents may be expanded by, for example, balloons. Furthermore, Applicant submits that the above definitions support both radially expanding at least the portion of the stent in the tube or allowing at least the portion of the stent to expand in the tube.

Applicant submits that "[the specification] need only be reasonable with respect to the art involved; they need not inform the layman nor disclose what the skilled already possess. They need not describe the conventional. . . . The intricacies need not be detailed ad absurdum." *General Electric Co. v. Brenner*, 159 USPQ 335, 337 (D.C. Cir. 1968). In addition, "[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed. *Ex parte Parks*, 30 USPQ 2d 1234, 1236B37 (B.P.A.I. 1993).

Accordingly, Applicant respectfully requests that the rejection of Claims 15-17 and 20-22 under 35 U.S.C. § 112 first paragraph be withdrawn at this time.

CLAIM REJECTIONS - 35 U.S.C. § 101

Applicant respectfully disagrees with the rejections of Claims 21-22 under 35 U.S.C. § 101 as allegedly having the same scope. Applicant submits that the two methods are distinguishable from one another. *Webster's Third New International Dictionary* (1993) defines "cure" as: "perfect by chemical change (as rubber by vulcanizing, plastics by treating with heat or chemicals to make them infusible or insoluble, or green concrete by maintaining proper conditions of moisture and temperature)". In comparison, *Webster's Third New International Dictionary* (1993) defines "polymerization" as: "a chemical reaction in which two or more small molecules combine to form larger molecules that contain repeating structural units of the original molecules and that have the same percentage composition as the small molecules if the small ones were all of the same kind".

Accordingly, Applicant respectfully submits that "curing the adhesive medium or allowing the adhesive medium to cure" in Claim 21 and "polymerizing the polymerisable composition" in Claim 22 are distinguishable and do not cover the same scope.

Accordingly, Applicant respectfully requests that the rejections of Claims 21-22 be withdrawn at this time.

CLAIM REJECTIONS - 35 U.S.C. § 103

Applicant respectfully disagrees with the rejection of Claims 15-17 and 20-22 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Nos. 5,015,253

MacGregor ('253), in view of 5,282,824 Gianturco ('824), 4,444,215 Kaster ('215), and optionally in view of 5,384,308, Simon et al ('308).

Claims 15-17 relate to methods of applying a covering layer to a stent and Claims 20-22 relate to methods of covering a stent. Applicant respectfully disagrees that it would have been obvious to one of ordinary skill in the art to position the stent **21** of MacGregor ('253) within a preformed cover and to bond the preformed cover to the stent. MacGregor ('253) is purportedly directed at a tubular endoprosthesis and a method for making the same. MacGregor ('253) purportedly discloses coating. For example, MacGregor ('253) discloses that "an appropriate material to form the strand will improve the biocompatibility and hemocompatibility of the stent **21**, these qualities may be enhanced further by the application or bonding of an appropriate coating directly to the exterior surface of the stent **21**." (See Column 5, lines 51-56). Applicant submits that no methods of bonding a covering are disclosed in MacGregor ('253) and that the purpose of the coating in MacGregor ('253) is directed at biocompatibility and hemocompatibility of the stent **21** rather than at a continuous covering on at least a portion of the stent in the present invention.

MacGregor ('253) provides no incentive for the methods of the present invention. Applicant respectfully submits that MacGregor ('253) does not teach, suggest or disclose the method including the steps of forming a tube made out of an elastomeric polymerisable composition, the tube having an inside; coating the inside of the tube with an adhesive medium; providing a stent having at least one portion along its length, and radially contracting the stent; inserting into the tube at least one portion of the stent; radially expanding the at least one portion of the stent in the tube

or allowing the at least one portion of the stent to expand in the tube; and curing the adhesive medium between the inside of the tube and the at least one portion of the stent in the tube.

Furthermore, Applicant submits that MacGregor ('253) does not teach, suggest or disclose other claimed methods including such steps as preparing an elastomeric composition dissolved in a solvent; coating the inside of the tube with the elastomeric composition dissolved in the solvent; evaporating the solvent; polymerizing the elastomeric composition between the inside of the tube and the at least one portion of the stent in the tube; and polymerizing the polymerisable composition.

Moreover, Applicant submits that MacGregor ('253) teaches away from the method Claims 15-17 and Claims 20-22 since MacGregor ('253) requires that the stent be "released" or "deployed" from the tubular body, such as a catheter. (See Column 2, lines 1-6). Thus, the tubular body of MacGregor ('253) cannot be polymerized, cured, or chemically bonded to the stent if the stent is being released or deployed from the tubular body. Applicant notes examiner's comment that MacGregor ('253) does not specifically recite covering the stent with a preformed tubular cover. (See paper 5, page 6, lines 5-6). Accordingly, MacGregor ('253) should not be utilized in combination with the secondary documents.

Gianturco ('824) purportedly is directed at vascular stent and discloses covering a stent with a sleeve 13 and stitching or gluing the joints 17 at either end of the stent assembly to the sleeve 13 (column 2, lines 40-65). Applicant submits that the Gianturco ('824) reference of stitching, gluing, embedding the stents in

plastic, and means for attaching the stents to the sleeve does not provide a teaching or disclosure of the present invention methods.

Kaster ('215) purportedly discloses using covering material on a graft or braided member and chemical curing of a synthetic material that adheres to the braided member (column 6, lines 33-44). Kaster ('215) teaches "additional deposition" of the plastic at column 7, lines 18-19 which Applicant submits would include a different method. Applicant submits that the Kaster ('215) reference does not provide a teaching or disclosure of the present invention methods.

Simon et al ('308) purportedly discloses a stent having an elastomeric sleeve (column 4, lines 32-47). Applicant submits that the specification makes no reference to bonding of the elastomeric sleeve and the stent. Applicant submits that Simon et al ('308) does not provide a teaching or disclosure of the present invention methods.

Applicant submits that the incentive to combine the teachings of the references is not apparent and "[o]bviousness cannot be established by combining the teaching of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. The prior art of record fails to provide any such suggestion or incentive." *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 USPQ 929, 932, 933 (Fed. Cir. 1984).

Furthermore, Applicant submits "[i]t is impermissible to use the claimed invention as an instruction manual or a template to piece together the teachings of the prior art so that the Claimed invention is rendered obvious. This court has

previously stated that [o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.” (quoting *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988). *In re Fritch*, 23 USPQ 2d 1780, 1784 (Fed. Cir. 1992).

Applicant submits that the subject matter as a whole would not have been obvious to a person of ordinary skill in the art at the time the invention was made.

In sum, applicant respectfully submits that neither MacGregor '253, in view of Gianturco '824, and Kaster '215, and optionally in view Simon et al '308 teach, disclose, or suggest the inventions as claimed in Claims 15-17 and 20-22 and therefore allowance is respectfully requested by Applicant at this time.

CONCLUSION

Applicant acknowledges that the following documents have been cited but not relied upon to reject the claims: U.S. Patent Nos. 5,591,222 to Susawa et al; 5,571,170 to Palmaz et al; 5,405,377 to Cragg; 5,383,928 to Scott et al; 5,282,860 to Matsuno et al; 5,151,105 to Kwan-Gett; 4,776,337 to Palmaz; and Foreign Patent 3,918,736 from Germany.

To conclude, applicant submits that Claims 15-17 and Claims 20-29 define subject matter patentable over the prior art of record. Claim 23 depends from Claim 15; Claim 24 depends from Claim 16; Claim 25 depends from Claim 17; Claim 26 depends from Claim 17; Claim 27 depends from Claim 20; Claim 28 depends from Claim 21; and Claim 29 depends from Claim 22.

In view of the above amendments taken together with the remarks herein, Applicants believe their Claims to be patentably distinct from the cited and applied documents and reconsideration and early allowance of the Claims is respectfully requested. Such favorable consideration is earnestly solicited.

Respectfully submitted,

Dated: September 5, 1997
Pfizer Inc.
Patent Department, 20th Floor
235 East 42nd Street
New York, NY 10017-5755
(612) 550-5650

Andrew D. Ryan
Andrew D. Ryan
Attorney for Applicant
Reg. No. 39,351